NDA 09-218/S-087

NOV 23 1998

DuPont Pharmaceuticals Company
Attention: Ms. Maida S. Burka
Chestnut Run Plaza, MR 2 116
P.O. Box 80721
Wilmington, DE 19880-072 1

Dear Ms. Burka:

Please refer to your supplemental new drug application dated April 22, 1997, received April 22, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coumadin (Warfarin Sodium Tablets, USP) Tablets and Coumadin (Warfarin Sodium for Injection, USP) for Injection.

We acknowledge receipt of your submissions dated July 30, 1997 and June 22, 1998.

This supplemental new drug application provides for: (1) a new packaging configuration of Coumadin Tablets, an HDPE bottle without an outer carton, (2) revisions to the "HOW SUPPLIED" section of the package insert, and (3) the attachment of the package insert directly to the HDPE bottle. During the course of the review, the Agency identified changes to the immediate container labels for the 30 and 100 count bottles.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling (package insert and immediate container labels submitted June 22, 1998) with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

A. Package Inserts:

1. At the end of the HOW SUPPLIED section, the following phrase should be changed

from: "$\mathbf{R}_{x\ only}$"

to: "$\mathbf{R}_{x}$ only".

B. Immediate Container Labels:

2. The following phrase should be changed

from: "R_x only"

to: "R_x only".

3. The trademark symbol “TM” for the color splash logo should be moved from other wording and abbreviations to avoid confusion as to what the “TM” is referencing.

These revisions are terms of the approval. Marketing the product before making the revisions, exactly as requested, in the product’s final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 09-218/S-087.” Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Karen Oliver, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

LT 11-23-98

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research